



1275 '99 MER 23 P2:14

March 15, 1999

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204 3/17/99

Dear Sirs:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR § 101.93, that Rexall Sundown, Inc. located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement within the last thirty days under the Sundown Herbals brand name bearing the following statement(s) on the label and/or in the labeling:

<u>Cat's Claw</u>: [It] promotes healthy immune function. Cat's Claw has been used traditionally to support healthy immune function and overall well-being. To further promote healthy immune function, take this product with Sundown Zinc Lozenges and Sundown Echinacea. Zinc is an important nutrient that helps to regulate the production of cells in the body's immune system. Echinacea enhances immune function to help you stay healthy.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely, Debarah Shur Anke

Deborah Shur Trinker

Vice President of Regulatory Affairs and Assistant General Counsel

Enclosure